Connecting Contact Lenses and Digital Technology

STATISTICAL ANALYSIS PLAN 4/27/2018

NCT02921087

Principal Investigator: Danielle Iacono, OD FAAO

Site: SUNY College of Optometry, 33 West 42nd Street, New York, NY, 10036

Phone: (212) 938-4052 | Fax: (212) 938-4182

CCDLT Study: Crossover Study – Analysis of Primary and Secondary Outcomes Statistical Methods:

In order to analyze the 2 x 2 crossover design for mainly the primary outcome, VAS, and secondary outcomes (CISS, CLDEQ, autorefraction, phoria), we utilized mixed model analysis, allowing the sequences of each subject to be modeled as repeated measures within PROC Mixed. We did not have period effects since there was no gap or wash-out period between the sequences. We obtained least-squares adjusted means from these and compared the difference between these as well. We also utilized two-sample two-sided t-tests when comparing certain secondary outcomes (pupil size, accommodation, logMAR, NRA, PRA) between lens preference at specific time points and/or between lens types. We utilized a 10% level of significance. SAS Version 9.4 was used for all analyses.